Reasons for Allowance

The following is an examiner's statement of reasons for allowance:

The prior art made of record does not teach or fairly suggest the combination of elements as recited in the independent claims. Specifically, the prior art does not teach limitations argued by applicant in Remarks filed 2/28/2011.

The dependent claims being definite, further limiting and fully enabled by the specification are also allowed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ronni S. Jillions on March 8, 2011.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty. Docket: **CLASSEN=6A**

In re Application of:	)	Conf. No.: **1273**
John Barthelow CLASSEN	)	Art Unit: **2161**
Appln. No.: **10/081,705**	)	Examiner: **E. P. Leroux**
Filed: **February 21, 2002**	)	Washington, D.C.
For: **COMPUTER ALGORITHMS AND METHODS FOR PRODUCT SAFETY**	)	**February 28, 2011**

EXAMINER AMENDMENT

Amendments to the Claims:

This listing of the claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claims 1 - 249 **(Canceled)**

250. **(Currently Amended)** A method of commercializing at least one previously unreported proprietary method of using a product of manufacture or device, wherein the proprietary method of using the product or device is established according to the steps comprising:

accessing one or more data sources, wherein at least one data source stores adverse event data associated with the product or device;

analyzing and comparing the stored adverse event data, with at least one previously-known adverse event associated with the product or device;

identifying at least one previously unreported essential adverse event associated with the product or device from the adverse event data, wherein an essential adverse event is one regulated by a regulatory agency requiring disclosure of the event in a package insert or data sheet accompanying the product or device, and

then responsive to identifying of the previously unreported essential adverse event, identifying at least one previously unreported method of use for the product or device associated with said identified essential adverse event;

documenting inventorship of the at least one previously unreported method of use for the product or device; and

creating a database of proprietary essential adverse event information, wherein the database stores at least one record related to at least one of: a patent, patent application, patent publication, or data contained in at least one patent, patent application or patent publication, wherein said at least one patent, patent application, patent publication, or data contained in at least one patent, patent application or patent publication, discloses and relates to at least one of the at least one previously unreported method of use and the at least one essential adverse event, and

wherein the at least one previously unreported proprietary method of using a product or device consists of a use selected from the group consisting of a restricted use of said product or device, providing warning(s) about the essential adverse event, providing instruction(s) for avoiding an essential adverse event, and any combination thereof; and

commercializing the at least one previously unreported proprietary method of using a product or device, the commercializing comprising exclusively disclosing the at least one previously unreported proprietary method of use and the associated at least one previously unreported

essential adverse event information, which information, once identified, must then accompany the product or device, wherein commercializing means creating profit from the exclusive disclosure.

251. **(Previously Presented)** The method of claim 250, further comprises determining value of commercializing the at least one use determined from the at least one identified essential adverse event, wherein the value depends on a potential value of making a generic product or device into a proprietary product or device, or preventing a proprietary product or device from becoming a generic product or device.

252. **(Cancelled)**

253. **(Previously Presented)** The method of claim 251, wherein the commercializing step further comprises generating information for incorporation into documents for selling, leasing or licensing the identified product information.

254. **(Previously Presented)** The method of claim 251, wherein the product is commercially available at the time of the analyzing step.

255. **(Previously Presented)** The method of claim 251, wherein the step of commercializing further comprises formatting the data relating to at least one adverse event associated with exposure to, or use of the product or device, or documenting same, such that a manufacturer or distributor of the product or device must inform consumers, users or individuals responsible for the user, physicians or prescribers about at least one adverse event associated with exposure to or use of the product or device.

256. **(Previously Presented)** The method of claim 250, wherein the product or device is commercially available at the time of the analyzing step, and wherein the at least one data source comprises information relating to patents and patent applications.

257. **(Previously Presented)** The method of claim 250, wherein the product or device is commercially available at the time of the analyzing step, and wherein the at least one data source comprises information relating to raw commercial or sales data, wherein said raw data is commercial or sales data before being processed and analyzed.

258. **(Previously Presented)** The method of claim 251, wherein the at least one adverse event comprises a drug interaction.

259. **(Previously Presented)** The method of claim 258, wherein the at least one data source comprises information relating to raw commercial or sales data, wherein said raw data is commercial or sales data before being processed and analyzed.

260. **(Previously Presented)** The method of claim 250, wherein the steps of establishing the use of the essential adverse event data are proprietary.

261. **(Previously Presented)** The method of claim 250, wherein the product is medical.

262. **(Previously Presented)** The method of claim 251, wherein the product is medical.

263. **(Previously Presented)** The method of claim 262, wherein the medical product is a generic drug.

264. **(Previously Presented)** The method of claim 250, wherein the product is non-medical.

265. **(Previously Presented)** The method of claim 251, wherein the product is non-medical.

266. **(Previously Presented)** The method of claim 250, wherein the device is medical.

267. **(Previously Presented)** The method of claim 251, wherein the device is medical.

268. **(Previously Presented)** The method of claim 250, wherein the device is non-medical.

269. **(Previously Presented)** The method of claim 251, wherein the device is non-medical.

270. **(Previously Presented)** A proprietary kit containing a product or device, and labeling listing the information which once identified, must accompany the product or device thus notifying a user of at least one previously unreported essential adverse event for the product or device, wherein the information to be listed on the labeling is determined in accordance with the method of claim 250.

271. **(Previously Presented)** A proprietary kit containing a product or device, and labeling listing the information which once identified, must accompany the product or device thus notifying a user of at least one previously unreported essential adverse event for the product or device, wherein information to be listed on the labeling is determined in accordance with the method of claim 259.

272. **(Previously Presented)** The method of claim 250, wherein the proprietary method of use is a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.

273. **(Previously Presented)** The method of claim 253, wherein the proprietary method of use is a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.

274. **(Previously Presented)** The method of claim 250, wherein the at least one adverse event is a drug interaction.

275. **(Previously Presented)** The method of claim 274, wherein the product or device is commercially available at the time of the analyzing step.

276. **(Previously Presented)** The method of claim 275, wherein the proprietary method of use comprises a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to, or use of, the product or device.

277. **(Previously Presented)** The method of claim 275, wherein at least one data source comprises information relating to raw commercial or sales data, wherein said raw data is commercial or sales data before being processed and analyzed.

278. **(Previously Presented)** The method of claim 277, wherein at least one previously unreported essential adverse event is other than a chronic immune mediated disorder.

279. **(Previously Presented)** The method of claim 277, the steps further comprising determining value of commercializing the at least one proprietary method of use determined from the at least one identified essential adverse event, wherein the value depends on a potential value of making a generic product or device into a proprietary product or device, or preventing a proprietary product or device from becoming a generic product or device.

280. **(Cancelled)**

281. **(Previously Presented)** The method of claim 250, wherein at least one previously unreported essential adverse event comprises a drug interaction, wherein at least one data source comprises information relating to patents and patent applications, and wherein at least one data source comprises information relating to raw commercial or sales data, wherein said raw data is commercial or sales data before being processed and analyzed.

282. **(Previously Presented)** The method of claim 251, wherein at least one previously unreported essential adverse event comprises a drug interaction, wherein at least one data source comprises information relating to patents and patent applications, and wherein at least one data

source comprises information relating to raw commercial or sales data, wherein said raw data is commercial or sales data before being processed and analyzed.

283. **(Previously Presented)** The method of claim 250, wherein the at least one adverse event data source comprises information regarding product postexposure adverse event data, which is recorded in selected time increments, ranging from less than one hour to more than ten years.

284. **(Previously Presented)** The method of claim 250, wherein the at least one adverse event data source comprises information regarding amount of use of the product or device or duration of exposure to the product or device by subjects.

285. **(Previously Presented)** The method of 250, wherein the at least one proprietary method of using the product or device is a restricted use in at least one population subgroup, where there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device and the previously unreported essential adverse event is one other than a chronic immune mediated disorder.

286. **(Previously Presented)** The method of claim 251, wherein the at least one proprietary method of using the product or device is a restricted use in at least one population subgroup, where there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device and the previously unreported essential adverse event is one other than a chronic immune mediated disorder.

287. **(Previously Presented)** The method of claim 250, wherein the product or device is commercially available, the steps further comprising identifying the proprietary method of use as a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.

288. **(Previously Presented)** The method of use claim 251, wherein the product or device is commercially available, the steps further comprising identifying the proprietary method of use as a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.

289. **(Cancelled)**

290. **(Previously Presented)** The method of claim 259, wherein the product or device is commercially available, the steps further comprising identifying the proprietary method of use as a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.

291. **(Previously Presented)** The method of claim 250, the steps further comprising documenting date of inventorship and storing information relating to the documented date of inventorship in the database of proprietary essential adverse event information.

292. **(Previously Presented)** The method of claim 250, wherein at least one adverse event data source comprises raw data from a plurality of different adverse events, wherein said raw data is commercial or sales data before being processed and analyzed.

293. **(Previously Presented)** The method of claim 250, wherein the product or device is commercially available, and the proprietary method of use is further identified as comprising restricting exposure of the product or device to at least one factor selected from the group consisting of high temperatures, low temperatures, chemicals, surfaces, pressures, electricity sparks; contact with an anatomical element selected from the group consisting of skin, eyes, ears, respiratory surfaces, gastrointestinal surfaces and mucous membranes of the user; exposure to a subpopulation group selected from the group consisting of children, pregnant women, users with

specific allergies, users with specific medical conditions, and animals; exposure to subpopulations defined by at least one user identifying characteristic selected from the group consisting of sex, weight, age, race, genetic characteristics, medical condition, pregnancy status, presence of allergies, use of drugs, use of tobacco, use of alcohol, and use of medical devices.

294. **(Previously Presented)** The method of claim 250, wherein at least one database of essential adverse event information is computerized.

295. **(Previously Presented)** The method of claim 250, wherein at least one data source comprises human adverse event data.

296. **(Previously Presented)** The method of claim 250, further comprising utilizing least one controlled clinical trial and or epidemiological study to discover at least one previously unreported essential adverse event.

297. **(Previously Presented)** The method of claim 250, wherein the step of establishing the adverse event is one other than an abnormal laboratory value.

298. **(Previously Presented)** The method of claim 250, wherein the use is one other than a new dosing regimen.

299. **(Previously Presented)** The method of claim 250, wherein the use further comprises providing printed product safety information in connection with product packaging.

300. **(Previously Presented)** The method of claim 251, wherein the use further comprises providing printed product warning information in connection with product packaging.

301. **(Previously Presented)** The method of claim 250, wherein the step of documenting the inventorship comprises storing information relating to the documented inventorship in the database of proprietary essential adverse event information.

302. **(Currently Amended)** A method of commercializing at least one previously unreported proprietary method of using a product of manufacture or device, comprising:

accessing one or more data sources, wherein at least one data source stores adverse event data associated with the product or device;

analyzing and comparing the stored adverse event data, with at least one previously-known adverse event associated with the product or device;

identifying at least one previously unreported essential adverse event associated with the product or device from the adverse event data, wherein an essential adverse event is one regulated by a regulatory agency requiring disclosure of the event in a package insert or data sheet accompanying the product or device, and

then responsive to identifying of the previously unreported essential adverse event, identifying at least one previously unreported method of use for the product or device associated with said identified essential adverse event;

documenting inventorship of the at least one previously unreported method of use for the product or device; and

creating a database of proprietary essential adverse event information, wherein the database stores at least one record related to at least one of: a patent, patent application, patent publication, or data contained in at least one patent, patent application or patent publication, wherein said at least one patent, patent application, patent publication, or data contained in at least one patent, patent application or patent publication, which discloses and relates to the at least one previously unreported method of use, and

wherein the at least one previously unreported proprietary method of use consists of a use selected from the group consisting of a restricted use of said product or device, providing warning(s) about the essential adverse event, providing instruction(s) for avoiding an essential adverse event, and any combination thereof, wherein the at least one previously unreported proprietary method of use is not a pharmacogenomic technique for screening; and

commercializing the at least one previously unreported proprietary method of use, the commercializing comprising exclusively disclosing the at least one previously unreported proprietary method of use and the associated at least one previously unreported essential adverse event information, which information, once identified, must then accompany the product or device, wherein commercializing means creating profit from the exclusive disclosure.

303 - 304. **(Cancelled)**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Etienne P. LeRoux whose telephone number is (571) 272-4022. The examiner can normally be reached on Monday through Friday, 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Apu Mofiz can be reached on (571) 272-4080. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Etienne P LeRoux/
Primary Examiner, Art Unit 2161

3/8/2011